

**IN THE UNITED STATES PATENT
AND TRADEMARK OFFICE**

Serial No. : 09/925,673
Applicants : Masakatsu KANEKO et al.
Filed : August 9, 2001
For : NOVEL NUCLEOSIDE AND
OLIGONUCLEOTIDE ANALOGUES
Art Unit : 1623
Examiner : Howard Owens, Jr.
Docket No. : 01376CIP/HG
Customer No.: 01933
Confirmation No.: 4630

MAIL STOP ISSUE FEE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**SECOND REQUEST FOR FULLY INITIALED
COPIES OF FORMS PTO/SB/08A DATED
NOVEMBER 7, 2001 AND SECOND REQUEST
FOR CORRECTED FORM PTO-892**

S I R :


A REQUEST FOR FULLY INITIALED COPIES OF FORMS PTO/SB/08A AND PTO/SB/08B AND REQUEST FOR CORRECTED FORM PTO-892 was filed on August 23, 2003 (the postcard receipt for which is enclosed). However, such REQUEST was not responded to.

The following is a reiteration of the REQUEST filed on August 25, 2003.

A. The Office Action of July 29, 2003 returned a copy of applicants' Form PTO/SB/08B (6 sheets dated November 7, 2001)

**NOTICE OF ALLOWANCE:
JANUARY 28, 2004**

Express Mail Mailing Label
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I hereby certify that this paper is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 with sufficient postage on the date indicated above and is addressed to the Commissioner for Patents,
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Dorothy DeFrancesco

In the event that this Paper is late filed, and the necessary petition for extension of time is not filed concurrently herewith, please consider this as a Petition for the requisite extension of time, and to the extent not tendered by check attached hereto, authorization to charge the extension fee, or any other fee required in connection with this Paper to Account No. 06-1378.

with the Examiner's initials in the left column next to each of the cited publications, except for the following two publications, which the Examiner drew lines through:

MARTIN, "A New Access to 2'-O-Alkylated Ribonucleosides and Properties of 2'-O-Alkylated Oligoribonucleotides", Helv. Chim. Acta., 1995, Vol. 78, pp. 486-504 (cited on sheet 2 of the Form PTO/SB/08B dated November 7, 2001, a copy of which is enclosed); and

HEGEMANN et al., "BIOCHEMICAL PHARMACOLOGY OF PROTEIN KINASE C AND ITS RELEVANCE FOR DERMATOLOGY", Pharmacol. of the Skin, 1992, Chapter 22, pp. 357-368 (cited on sheet 3 of the Form PTO/SB/08B dated November 7, 2001, a copy of which is enclosed.).

No reasons were set forth in the July 29, 2003 Office Action as to why the above two publications were not initialed by the Examiner.

The MARTIN publication is in German, but includes on the first page thereof an English-language abstract which is reproduced as follows:

"A New Access to 2'-O-Alkylated Ribonucleosides and Properties of 2'-O-Alkylated Oligoribonucleotides

A general access to 2'-O-alkylated ribonucleosides using the key intermediate 5 is presented. The incorporation of 2'-O-ethyleneglycol- and 2'-O-glycerol-substituted (i.e., 2'-O-(2-hydroxyethyl)- and 2'-O-(2,3-dihydroxypropyl)-substituted) ribonucleosides into oligonucleotides affords a new generation of oligonucleotides with high affinity for RNA, high specificity, and increased nuclease resistance."

The MARTIN publication is also discussed in the paragraph bridging pages 11 and 12 of the specification as follows:

"Preferred 2'-groups of the sugar include H, OH, F, and O--, S--, or N-alkyl groups. One particularly preferred group includes 2'-methoxyethoxy[2'--O--CH₂CH₂OCH₃, also known as 2'-O-(2-methoxyethyl) or 2'-MOE] (Martin et al., Helv. Chim. Acta., 1995, 78, 486), i.e., an alkoxyalkoxy group."

It is respectfully submitted that the above information concerning the MARTIN publication provides a concise explanation of the relevance of the MARTIN publication in compliance with 37 CFR 1.98(a)(3)(i).

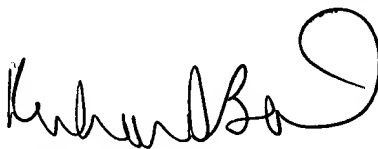
The HEGEMANN et al. publication (which is discussed in the paragraph bridging pages 21 and 22 of the specification) is Chapter 22 in a book entitled "Pharmacology of the Skin", edited by Hasan Mukhtar. It is considered that the Examiner may have not realized that the HEGEMANN et al. citation was included in this book. A copy of the HEGEMANN et al. citation is enclosed for the convenience of the Examiner.

Copies of sheets 2 and 3 of the Form PTO/SB/08B dated November 7, 2001 are enclosed.

In view of the above, it is respectfully requested that the Examiner provide the undersigned with fully initialed copies of sheets 2 and 3 of the Form PTO/SB/08B dated November 7, 2001.

B. The July 29, 2003 Office Action included a Notice of References Cited (Form PTO-892) which cited "WO 98/39532" to Imanishi et al. This citation is incorrect. The correct citation is "WO 98/39352" (see sheet 1 of applicants' Form PTO/SB/08A dated October 31, 2001, wherein WO 98/39352 is cited). Please correct the Patent Office records accordingly, and please issue a corrected Form PTO-892.

Respectfully submitted,



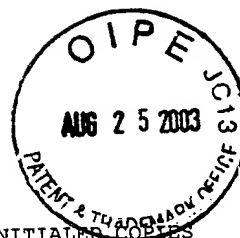
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RSB/ddf

- Encs.: (1) copy of postcard receipt dated
August 25, 2003
- (2) copies of sheets 2 and 3 of the Form
PTO/SB/08B dated November 7, 2001
- (3) copy of HEGEMANN et al., "BIOCHEMICAL PHARMACOLOGY
OF PROTEIN KINASE C AND ITS RELEVANCE FOR
DERMATOLOGY", Pharmacol. of the Skin, 1992, Chapter
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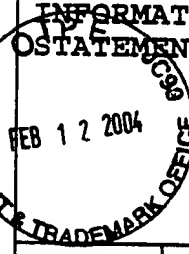
Attorney Docket: 01376CIP/HG
Serial No.: 09/925,673
Applicants: Masakatsu KANEKO et al.
Filed : August 9, 2001



RECEIPT ACKNOWLEDGED: REQUEST FOR FULLY INITIALED COPIES
OF FORMS PTO/SB/08A AND PTO/SB/08B AND REQUEST FOR
CORRECTED FORM PTO-892, including copy of HEGEMANN et al.,
"BIOCHEMICAL PHARMACOLOGY OF PROTEIN KINASE C AND ITS
RELEVANCE FOR DERMATOLOGY", Pharmacol. of the Skin, 1992,
Chapter 22, pp. 357-368.

fcm/cert. of mailing: August 20, 2003

RSB/ddf

Substitute for Form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT 				Application Number	09/925,673
				Filing Date	August 9, 2001
				First Named Inventor	Masakatsu KANEKO et al
				Group Art Unit	1623
				Examiner Name	
Sheet	2	of	6	Attorney Docket Number	01376CIP/HG
OTHER PRIOR ART - NON-PATENT LITERATURE DOCUMENTS					
Examiner Initials ¹	Cite No. ¹	Include name of author (in CAPITAL LETTERS), title of article, title of item, date, page(s), volume-issue number(s), publisher, city and/or country where published			T ²
		MANOHARAN et al, "INTRODUCTION OF A LIPOPHILIC THIOETHER TETHER IN THE MINOR GROOVE OF NUCLEIC ACIDS FOR ANTISENSE APPLICATIONS", <u>Bioorg. Med. Chem. Lett.</u> , 1993, Vol. 3, No. 12, pp. 2765-2770. MANOHARAN et al, "CHOLIC ACID-OLIGONUCLEOTIDE CONJUGATES FOR ANTISENSE APPLICATIONS", <u>Bioorg. Med. Chem. Lett.</u> , 1994, Vol. 4, No. 8, pp. 1053-1060. LISBY et al, "Intercellular adhesion molecule-1 (ICAM-1) expression correlated to inflammation", <u>Br. J. of Dermatol.</u> , 1989, <u>120</u> , 479-484. MAHER III, "Prospects for the Therapeutic Use of Antigene Oligonucleotides", <u>Cancer Investigation</u> , 1996, <u>14(1)</u> , pp. 66-82. BIRKEDAL-HANSEN, "Proteolytic remodeling of extracellular matrix", <u>Current Op. Biol.</u> , 1995, <u>7</u> , pp. 728-735. LeROITH et al, "Molecular and Cellular Aspects of the Insulin-Like Growth Factor I Receptor", <u>Endocr. Rev.</u> , 1995, Vol. 16, No. 2, pp. 143-163. KABANOV et al, "A new class of antivirals: antisense oligonucleotides combined with a hydrophobic substituent...", <u>FEBS Lett.</u> , Jan. 1990, Vol. 259, No. 2, pp. 327-330. MARTIN, "A New Access to 2'-O-Alkylated Ribonucleosides and Properties of 2'-O-Alkylated Oligoribonucleotides", <u>Helv. Chim. Acta</u> , 1995, Vol. 78, pp. 486-504. DeLISSER et al, "Molecular and functional aspects of PECAM-1/CD31" <u>Immunol. Today</u> , 1994, Vol. 15, No. 10, pp. 490-495. HIMELSTEIN et al, "Metalloproteinases in Tumor Progression: The Contribution of MMP-9", <u>Invasion Metastasis</u> , 1994-95, <u>14</u> , pp. 246-258.			
Examiner Signature				Date Considered	

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPSP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Place a check here if English translation is attached.

DATE MAILED: **November 7, 2001**



Substitute for Form 1449A/PTO

Application Number

09/925,673

Filing Date

August 9, 2001

First Named Inventor

Masakatsu KANEKO et al

Group Art Unit

1623

Examiner Name

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

Sheets

3

of

6

Attorney Docket Number

01376CIP/HG

OTHER PRIOR ART - NON-PATENT LITERATURE DOCUMENTS
Examiner
Initials¹Cite
No.¹

Include name of author (in CAPITAL LETTERS), title of article, title of item, date, page(s), volume-issue number(s), publisher, city and/or country where published

T²

HO et al, "Treatment of severe lichen planus with cyclosporine", J. Am. Acad. Dermatol., 1990, Vol. 22, No. 1, pp. 64-68.

GUM et al, "Stimulation of 92-kDa Gelatinase B Promoter Activity by ras Is Mitrogen-activated Protein Kinase...", J. Biol. Chem., 1996, Vol. 271, No. 18, pp. 10672-10680.

LITWIN et al, "Novel Cytokine-independent Induction of Endothelial Adhesion Molecules Regulated by Platelet/Endothelial Cell Adhesion Molecule (CD31)", J. Cell Biol., 1997, Vol. 139, No. 1, pp. 219-228.

NEWMAN, "Perspective Series: Cell Adhesion in Vascular Biology", J. Clin. Invest., 1997, Vol. 99, No. 1, pp. 3-8.

HAKUGAWA et al, "The Inhibitory Effect of Anti-Adhesion Molecule Antibodies on Eosinophil...", J. Dermatol., 1997, Vol. 24, pp. 73-79.

DEMERS et al, "Enhanced PCR amplification of VNTR locus D1S80 using peptide nucleic acid (PNA)", Nucl. Acid Res., 1995, Vol. 23, No. 15, pp. 3050-3055.

SHEA et al, "Synthesis, Hybridization properties and antiviral activity of lipid-oligodeoxynucleotide conjugates", Nucl. Acid Res., 1990, Vol. 18, No. 13, pp. 3777-3783.

OBERHAUSER et al, "Effective incorporation of 2'-O-methyl-oligoribonucleotides into liposomes and enhanced cell association...", Nucl. Acid Res., 1992, Vol. 20, No. 3, pp. 533-538.

REGESI et al, "Vascular adhesion molecules in oral lichen planus", Oral Surg. Oral Med. Oral Pathol. Oral Radiol. Endod., 1996, Vol. 81, No. 6, pp. 682-690.

HEGEMANN et al, "BIOCHEMICAL PHARMACOLOGY OF PROTEIN KINASE C AND ITS RELEVANCE FOR DERMATOLOGY", Pharmacol. of the Skin, 1992, Chapter 22, pp. 357-368.

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